

PATENT

Serial No. 08/372,676

Docket No. 304142800300

Docket No. 434-047

N.F. 47- (New) The method of claim 44, wherein the individual is suspected of having a cancer selected from the group consisting of melanoma, neuroblastoma, glioma, sarcoma, and small cell carcinoma.

E3 18 48. (New) A method for detecting an anti-GD2 antibody in a biological sample, comprising the steps of providing the diagnostic kit of claim 34; and contacting the antibody provided in the container with any anti-GD2 antibody in the biological sample.

### REMARKS

By way of this amendment, claim 40 is amended, and claims 42-48 are added.

Claim 40 is amended to correct a typographical error.

New claims 42 and 43 recite methods for preparing monoclonal antibody 1A7 by purifying antibody from an antibody-producing cell line, or growing the cell line. These claims depend from claim 28, and incorporate all the limitations of claim 28 with respect to the hybridoma or the progeny thereof. Purification of 1A7 antibody from the hybridoma line is taught in the disclosure, *inter alia*, on page 15, lines 10-12. The hybridoma was grown to prepare 1A7 during culturing and cloning (page 13, line 33 to page 14, line 2), and during preparation of ascites fluid (page 15, lines 7-10). As indicated throughout the disclosure, monoclonal antibody 1A7 prepared by this method is useful, *inter alia*, for raising an active response against ganglioside GD2.

New claims 44-47 recite methods for eliciting immunity or antibody reactive against ganglioside GD2, comprising administering a monoclonal antibody. These claims depend from claim 27, and incorporate all the limitation of claim 27 with respect to an antibody having all the identifying characteristics of monoclonal antibody 1A7. The use of 1A7 to generate active immunity against GD2 antigen is supported in the disclosure, *inter alia*, on

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page 8, lines 23-35. The use of 1A7 to generate anti GD2 antibody is supported, *inter alia*, on page 15, line 16 to page 16, line 13. The use of 1A7 mixed with QS-21 to generate an anti-GD2 response is supported, *inter alia*, on page 16, lines 7-13. Claim 47 recites raising an anti-GD2 response in the context of certain cancers that are also listed in allowed claim 40. Examples of utility for an anti-GD2 response described in the disclosure include reactivity against GD2 on tumor cells in an immunized subject (page 12, lines 33-36), and preparation of anti-GD2 (page 16, lines 14-21) for use in distinguishing between different gangliosides (page 17, line 27 to page 18, line 4) and different cancer cells (page 18, lines 5-11).

New claim 48 recites a method for detecting anti-GD2 antibody using a diagnostic kit of this invention. This claim depends from claim 34, and incorporates all the limitations with respect to the antibody contained in the kit. The detection of anti-GD2 activity by contacting the 1A7 antibody with a biological sample is supported, *inter alia*, on page 15, lines 26-29. Detecting anti-GD2 levels is useful, *inter alia*, in monitoring an individual's response to the administration of monoclonal antibody 1A7 (page 15, lines 26-29).

No new matter is added to the disclosure as a result of the amendments put forward herein.

The added claims conform to the requirements outlined in a recent document from the Office of Patent Policy Dissemination of the U.S. Patent Office, entitled "Training Materials for Treatment of Product and Process Claims in Light of *In re Brouwer* and *In re Ochiai* and 35 USC 103(b)", dated July 25, 1996. The document indicates that claims to methods of making or using an allowed product are also allowable without reopening substantive prosecution, providing they are supported in the specification and contain all the limitations of the product. See especially the last paragraph on page 4, and Example 1 on page 7. As indicated above, each of the added claims incorporate all the limitations of an allowed claim, and are supported in the specification.

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Claims to a method of making antibody 1A7 or eliciting an immune response have not previously been presented in the subject application, and have therefore not been considered with respect to U.S. restriction practice. The document from the Office of Patent Policy Dissemination instructs that upon allowance of product claims, process claims incorporating the same limitations otherwise subject to restriction are rejoined into the elected group (fourth paragraph on page 3, and Example 2). Accordingly, the claims added by way of this amendment fall within the elected group, and may be considered for allowance as part of the subject application.

The added claims conform to the guidelines suggested for acceptance of new claims under 37 CFR § 1.312(a), as outlined in MPEP §§ 714.14 and 714.16. The added claims are needed because they protect the making or using of compositions of the invention. No additional search is required because the claims incorporate limitations of allowed product claims, and are obviously allowable as outlined in the preceding paragraph. Hence, entry of the new claims will not involve materially added work by the Office. The new claims are being presented now because the document referred to came to the attention of applicants' attorneys after mailing of the Notice of Allowance.

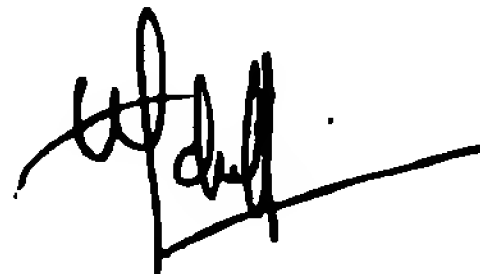
Accordingly, applicants respectfully request that the amendment be entered and that the new claims be allowed as part of the patent issued for the subject application.

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If the Examiner believes there are any outstanding matters to be resolved, she is invited to telephone applicants' agent at the telephone number listed below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension or other relief is required, applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of this document to our **Deposit Account No. 03-1952**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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